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GE Medical Systems
Information Technologies
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8200 West Tower Avenue
Milwaukee, Wisconsin, 53223

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: March 4, 2013

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Device: Trade Name: Monitor B40
Common/Usual Name: Multi-parameter patient monitor
Classification Names: 21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Primary Product Code: MHX
Secondary Product Codes: BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ
Predicate Device(s): K120598 Monitor B40
K102239 CARESCAPE Monitor B650
K123195 CARESCAPETM Respiratory Modules

Device Description: The proposed Monitor B40V2 is a multi-parameter patient monitor that is developed based on the predicate Monitor B40V1 (K120598) platform. The proposed Monitor B40V2 provides additional support for optional modules (E-Entropy module (K061907) and CARESCAPE Respiratory modules (E-sCO and E-sCAiO) (K123195) compared with predicate Monitor B40V1 (K120598). The proposed Monitor B40V2 is also compatible with CARESCAPE Respiratory modules (E-sCOV and E-sCAiOV)(K123195) but with disabled spirometry function.

The proposed Monitor B40V2 utilizes the existing 12 inch LCD display with an integrated keypad and a pre-configuration patient parameter measurement module. The proposed Monitor B40V2 will continue to interface with the optional E-MiniC (K052582) and Thermal Recorder with an extension rack.

As with the predicate Monitor B40V1, the proposed Monitor B40V2 includes features and subsystems that are optional or configurable. The proposed Monitor B40V2 interfaces to a variety of existing central station systems via a cabled network interface.

As with the predicate Monitor B40V1, the proposed Monitor B40V2 has a mounting plate on the bottom of the monitor. The monitor can be mounted in a variety of ways (e.g. shelf, countertop, table, wall, pole, or head/foot board) using existing mounting accessories.

Intended Use: The Monitor B40 is a portable multi-parameter unit to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

The Monitor B40 is intended for use under the direct supervision of a licensed health care practitioner.

The Monitor B40 is not intended for use during MRI.

The Monitor B40 can be a stand-alone monitor or interfaced to other devices via a network.

The Monitor B40 monitors and displays: ECG (including ST segment, arrhythmia detection), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen

saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring.

Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.

Technology: The proposed Monitor B40V2 is a modified system based on the predicate Monitor B40V1 (K120598). The proposed Monitor B40V2 provided additional supporting for optional modules (E-Entropy module (K061907) and CARESCAPE Respiratory modules (K123195).

The proposed Monitor B40V2 uses the identical hemodynamic module (Hemo module) as the predicate Monitor B40V1 (K120598) in the monitoring of ECG, Resp, NIBP, IBP, SpO2 and Temp parameters data. The only exception is the neonate application is now enabled by the main software for GE Trusingal SpO2 in the proposed Monitor B40V2.

The proposed Monitor B40V2 uses identical E-MiniC module (K052582) as the predicate Monitor B40V1 (K120598).

The proposed Monitor B40V2 uses the identical E-Entropy module (K061907) as the predicate device CARESCAPE Monitor B650 (K102239).

The proposed Monitor B40V2 uses the identical CARESCAPE respiratory modules (E-sCO and E-sCAiO) which cleared in K123195.

The proposed Monitor B40V2 is also compatible with CARESCAPE Respiratory modules (E-sCOV and E-sCAiOV) (K123195) but the Spirometry function is disabled.

More comparison information can be found in Comparison Matrix in Section 12.1.

The fundamental technology of the proposed Monitor B40V2 is the same as the predicate devices.

The proposed Monitor B40V2 is as safe and effective as the predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The proposed Monitor B40V2 and its applications comply with voluntary standards as detailed in this premarket submission. The following quality assurance measures were applied to the development of the system:

- ☐ Risk Analysis
- ☐ Requirements Reviews
- ☐ Design Reviews
- ☐ Testing on unit level (Module verification)
- ☐ Integration testing (System verification)
- ☐ Final acceptance testing (Validation)
- ☐ Performance testing (Verification)
- ☐ Safety testing (Verification)

Summary of Clinical Tests:

The predicate Monitor B40V1(K120598) utilized the GE SpO2 TruSignalV2 algorithm. But disabled SpO2 function for neonatal patient type. The proposed Monitor B40V2 used identical GE SpO2 TrusingalV2 algorithm with predicate Monitor B40V1(K120598) but enabled SpO2 function for Neonatal patient type in main software.

Clinical study of the GE SpO2 TruSignalV2 on Neonatal patient population was performed in accordance to ISO 14155-1, ISO14155-2, ISO9919 and FDA Guidance.

The results of the clinical study demonstrated SpO2 accuracy performance of the TruSignal V2 technology on the neonate population.

Detail clinical study information can be found in Section 20.

Conclusion: GE Healthcare considers the proposed Monitor B40V2 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 26, 2013

Ge Medical Systems China Co., Ltd.
Mr. Robert Casarsa
8200 West Tower Ave
Milwaukee, WI 53223 US

Re: K130584
Trade/Device Name: Monitor b40
Regulation Number: 21 CFR 870.1025
Regulation Name: Multiparameter Patient Monitor (Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DSB, DSK, GWQ, FLL, NHO, NHP, NHQ
Dated: May 28, 2013
Received: May 29, 2013

Dear Mr. Robert Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: **Monitor B40**

Indications for use:

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Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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